# MISSOURI BOARD OF PHARMACY



# ANNUAL REPORT



FY 2023



Michael L. Parson, Governor State of Missouri

Chlora Lindley-Myers, Director Department of Commerce and Insurance

Sheila Solon, Division Director Division of Professional Registration





Michael L. Parson Governor State of Missouri

# Sheila Solon, Division Director DIVISION OF PROFESSIONAL REGISTRATION

Department of Commerce and Insurance Chlora Lindley-Myers, Director

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To The Honorable Governor Michael L. Parson:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2023 ("FY 23"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours, MISSOURI BOARD OF PHARMACY By:

Kimberly Grinston Executive Director



# Department of Commerce and Insurance Division of Professional Registration Missouri Board of Pharmacy

### FY 2023

#### **Board Members**

James Gray, PharmD., President
Christian Tadrus, PharmD., Vice-President
Colby Grove, PharmD., Member
Douglas Lang, R.Ph., Member
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph., Member
Anita K. Parran, Public Member

#### Missouri Board of Pharmacy

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Kimberly A. Grinston, J.D., Executive Director

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# Executive Summary



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2022 to June 30, 2023 (FY23). The Board is pleased to announce another successful regulatory year as reflected below:

#### **Board Operations**

- The Board held twenty-five (25) meetings during FY 23, including, seventeen (17) regular meetings, four (4) email ballot meetings and four (4) Board Rx Cares Sub-Committee meetings. In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held three (3) virtual meetings facilitated by the Board. Two Board members also serve on the Joint Oversight Task force for the Prescription Drug Monitoring Program.
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted seven (7) educational webinars. Educational programs were free and Board approved for pharmacist continuing education.

#### Financial Overview

- The Board's total appropriation and authorized transfers for FY 23 were \$4,013,046. Board expenditures remained consistent with a total of \$2,910,479.58 (-3.76%).
- Board revenue increased by 21% to \$3,662,095.12, primarily attributable to an increase in new pharmacy business license fees and individual renewal fees.

### **Licensing Summary**

- The Board's total licensee/registrant count remained consistent with 37,782 licensees/registrants at the close of the fiscal year (-1.2%), as reflected below:
  - O Drug Distributors: 1,344 (+3.5%)
  - O Drug Distributor Registrants: 100 (+4.16%)
  - O Drug Outsourcers: 47 (+9.3%)
  - O Intern Pharmacists: 1,264 (-28%)
  - O Pharmacies: 2,842 (+8%)
  - O Pharmacists (Active and Inactive): 11,833 (-2.9%)
  - O Pharmacy Technicians 20,100 (+0.44%)
  - O Temporary Pharmacists: 11 (-15%)
  - O Third-Party Logistics Providers: 241 (+17.5%)
- New licensees/registrations in FY23 decreased to 6,751 (-6.5%) as reflected below:
  - O Drug Distributors: 89 (-31%)
  - O Drug Distributor Registrants: 6 (+20%)
  - O Drug Outsourcers: 5 (No Change)
  - O Intern Pharmacists: 359 (-2.4%)
  - O Pharmacies: 350 (+66%)
  - O Pharmacists (Active and Inactive): 457 (-10.9%)
  - O Pharmacy Technicians: 5,439 (-8.5%)
  - O Temporary Pharmacists: 7 (-30%)
  - O Third-Party Logistics Providers: 39 (-14.7)
- Total licensed pharmacies increased by 8% to 2,842 licensed pharmacies (1,433 in-state, 1,324 non-resident, 75 temporary). Two (2) Missouri counties do not have a licensed pharmacy (Schuyler & Knox); Sixteen (16) Missouri counties have only one licensed pharmacy.

# Executive Summary



### Complaint Handling

- The Board received/opened 507 complaints in FY 23, representing a 27.2% decrease from FY 22. The decrease is
  primarily attributable to a decline in complaints/cases related to the Board's pharmacist continuing education audit
  given FY 23 was not an audit year. Additionally, no tax compliance cases/complaints were referred from the Missouri
  Department of Revenue during FY 23.
- The Board issued final dispositions on 624 complaints/cases in FY 23; all of the closed complaints/cases were nontax related.
- Of the 624 non-tax related complaint dispositions, 89.3% resulted in no disciplinary action (557 cases), while disciplinary action was taken in the remaining 10.7% (67 cases).

### **Disciplinary Actions**

 The Board issued sixty-seven (67) practice related disciplinary actions in FY 23, representing a 14% decrease from FY 22.

#### Inspections/Investigations

- 1,034 regulatory inspections were conducted during the fiscal year (-4.3%). Approximately 66.2% of Board inspections resulted in regulatory violations (violations noted/compliance notices).
- Total completed investigations increased by 8.7% to 285 completed investigations.

#### Compounded Drug Testing

 Pursuant to § 338.150, RSMo, the Board conducts a testing program for drug preparations compounded by licensed pharmacies. 70.8% of products tested in FY 23 were satisfactory while 29.2% were unsatisfactory. Failing potency results ranged from 42.8% to 154.8%.

### Rulemaking

- The Board continued its review of Missouri's pharmacy rules to ensure appropriate and consistent regulation.
- Eight (8) administrative rules were adopted or amended in FY 23 (new, amendment, and emergency). The board submitted one (1) legislative proposal for approval by the Governor to clarify/expand authorized pharmacist services to address a public health need.

#### Rx Cares for Missouri

- The Board expended \$144,476.55 for the Rx Cares for Missouri Program in FY 23: \$92,789.52 in Rx Cares grant funding/educational activities, \$51,590 for the Rx Cares medication destruction/disposal program, and \$97.03 in miscellaneous mailing costs.
- One-hundred and seventeen (117) entities participated in the medication destruction/disposal program in FY 23, including pharmacies, hospitals, and local law enforcement agencies.
- Approximately 15,518 pounds of unwanted medication was destroyed in FY 23 under the Rx Cares Medication destruction program. Approximately 36,827 pounds of unwanted medication have been destroyed since initial program implementation in FY 20 (@ 18.4 tons).

# About the Board



#### Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- · Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

#### ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Commerce and Insurance.

#### **MEMBERSHIP**

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

#### **FUNCTIONS**

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies, drug distributors, drug outsourcers and third-party logistics providers;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/ registrant;
- Inspection of pharmacies, drug distributors, drug outsourcers and third-party logistics providers; and
- Approval of preceptors and intern training facilities.

# **Board Operations**



### General Board Operations

The Board held twenty-five (25) meetings during FY 23, including seventeen (17) regular meetings, four (4) email ballot meetings, and (4) Board Rx Cares Sub-Committee meetings.\* In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held three (3) virtual meetings facilitated by the Board.\* Board Members Douglas Lang and Christian Tadrus also serve on the Joint Oversight Task force for the Prescription Drug Monitoring Program.

\*Public attendees were able to virtually attend open session meetings.

#### Staff

The following staff were employed by the Board at the close of FY23:

#### Staff

- Kimberly Grinston, J.D., Executive Director
- · Jennifer Boehm, Administrative Coordinator
- Semaja Smith, Pharmacy Technician Coordinator
- Kim Hatfield, Compliance Coordinator
- Mary Blevins, Pharmacy/Drug Distributor Coordinator
- · Erika Wright, Pharmacist Coordinator

#### Inspectors

- Tom Glenski, R.Ph., Chief Inspector
- · Katie DeBold, PharmD.
- Andrea "Andi" Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Everett, R.Ph.
- Natalie Foster, PharmD.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

\*Inspector Bennie Dean, R.Ph., retired in FY 23

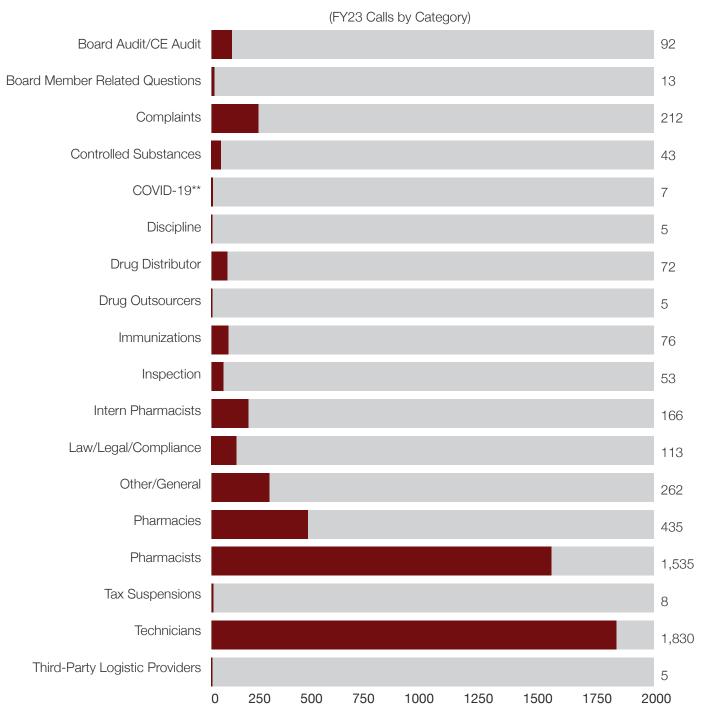
# **Board Operations**



#### Office Activities

The Board received/responded to 4,932 telephone calls during FY 23, representing a 16.49% decrease from FY 22 likely attributable to an increase in available online services/information. Board inspectors received an additional 395 telephone calls.

Major topic areas for calls received by the Board office are identified below:



<sup>\*</sup> Pharmacist category includes licensing, continuing education and audit related questions.

<sup>\*\*</sup>COVID-19 related calls may have also been recorded in other categories (e.g. Law/Legal/Compliance/Immunizations/Pharmacy/etc.

# **Board Operations**



#### Education/Training

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY 23 (participants were awarded free continuing education credit):

- 2022 Legislative Update
- 2022 Sterile Compounding Update
- 2022 Compliance Update/Inspector Q&A
- 2023 New Graduate/MPJE Update
- 2023 Pharmacy Technician Update
- 2023 Drug Distributor/Third-Party Logistics Provider Compliance Update
- 2023 MO HealthNet Pharmacy Program Update

#### Legislative Proposals

The following legislative proposal was approved by the Board for the 2023 legislative session:\*\*

 Emergency Response Authority: Allows pharmacists to order and administer medication as approved or authorized by the U.S. Food and Drug Administration (FDA) to address a public health need during a state/ federally declared public health emergency, or as authorized by the Missouri Department of Health and Senior Services to address a public health need.

#### Gold Certificates

The following individuals received Gold Certificates during FY 23 representing fifty (50) years of licensure as a Missouri pharmacist:

- · Ryon L. Adams
- David Allen
- Sara H. Bagby
- Ronald L. Bashor
- Joel J. Bertrand
- Richard E. Cowan
- Brenda J. Denton
- Mary R. Grear
- Victor A. Heisserer
- Paul E. Hendricks
- Frank J. Hollenback
- Jerry D. Jones
- William K. Kenney
- Sidnev G. Kent
- Sam L. Mahoney

- George W. Mcconnell
- David J. Meador
- · Thomas L. Mever
- Patricia J. Middeke
- Pamela J. Mitchell
- John W. Morgan
- Lynn A. Morris
- Paula R. Post
- Michael P. Schaller
- Margaret A. Sgritta
- John E. Sherwood
- Jane S. Tennis
- Dana E. Wilcox
- Clarence R. Wooderson

<sup>\*\*</sup> Section 324.035 was enacted in FY 20 which prohibits professional/occupational boards within the Division of Professional Registration from using Board funds to provide designated continuing education classes.

<sup>\*\*</sup> Legislative proposals are subject to Governor approval.

# Financial Summary



#### Financial Overview:

The Missouri Board of Pharmacy's appropriation for the fiscal year ending June 30, 2023, was as follows:

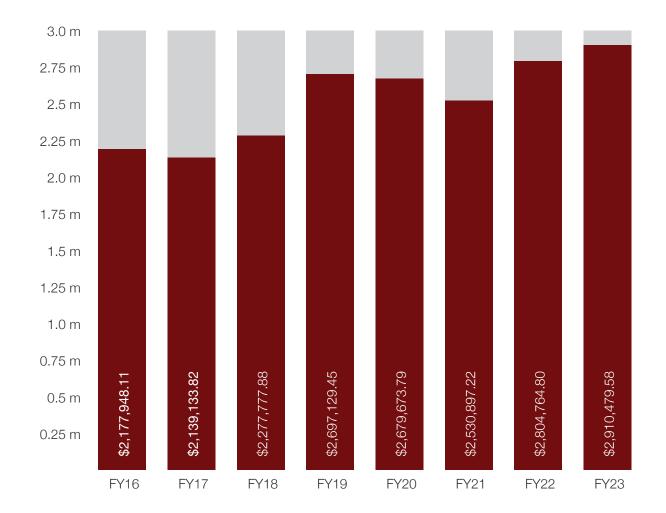
Personal Service \$ 1,345,772.00 Expense and Equipment \$ 1,420,086.00 Criminal History Fund \$ 5,000.00 Transfers\* \$ 1,242,188.00 \$ 4,013,046.00

Of the amount appropriated, the Board expended \$2,910,479.58 in FY 21 as follows:

Personal Service \$ 1,289,762.81 (44%) Expense and Equipment \$ 546,602.45 (19%) Transfers\* \$ 1,074,114.32 (37%)

\*Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.

FY 23 expenditures remained consistent with a minor 3.76% increase from FY 23.



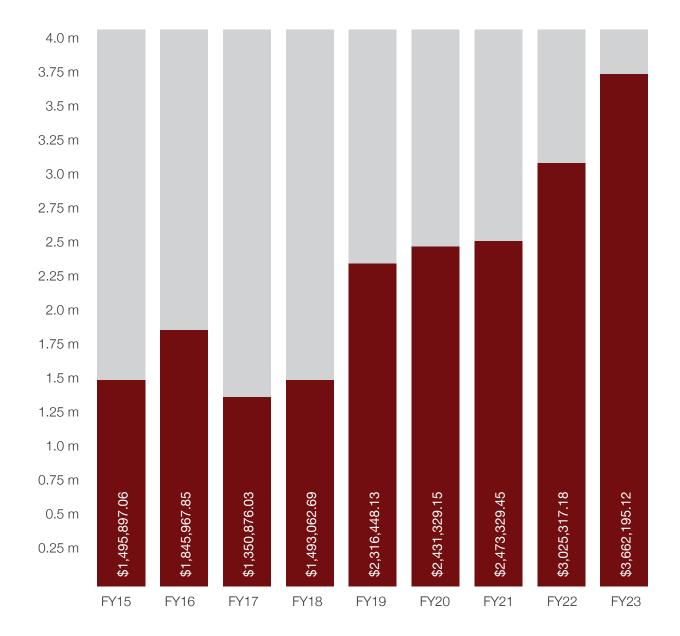
# Financial Summary



#### Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338.

Board revenue increased in FY23 by 21%, primarily attributable to an increase in new pharmacy license fees and individual renewal fees. The Board will continue to monitor future revenue trends to ensure compliance with § 338.070, RSMo.



# Licensing



### **Licensing Summary**

Pursuant to Chapter 338, RSMo, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers.

The Board's total licensee/registrant count remained consistent with 37,782 licensees/registrants at the close of the fiscal year (37,498 active/285 inactive), as reflected below:

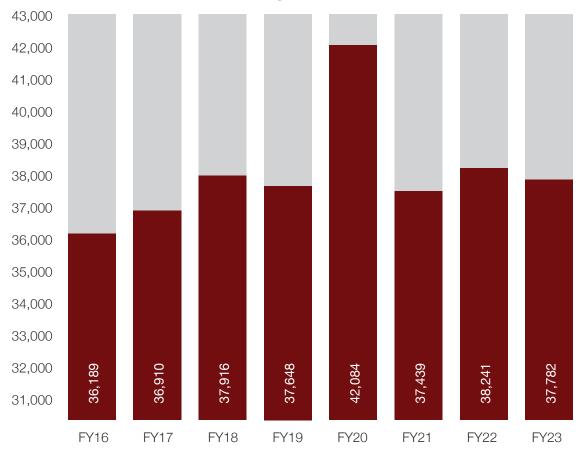
LICENSING TOTALS	6
Drug Distributors (licensed & temporary)	1,344 (+3.5%)
Drug Distributor Manufacturer Registrants	100 (+4.16%)
Drug Outsourcers	47 (+9.3%)
Intern Pharmacists	1,264 (-28%)
Pharmacists (active and inactive)	11,833 (-2.9%)
Pharmacists (temporary)	11 (-15%)
Pharmacies (instate, non-resident and temporary)	2,842 (+8%)
Pharmacy Technicians	20,100 (+.44%)
Third-Party Logistics Provider (licensed & temporary)	241 (+17.5%)
TOTAL	37,782 (-1.2%)

While total license counts remained stable, new licensees/registrations decreased to 6,751 new licensees/registrants issued in FY 23 (-6.5%) as reflected below:

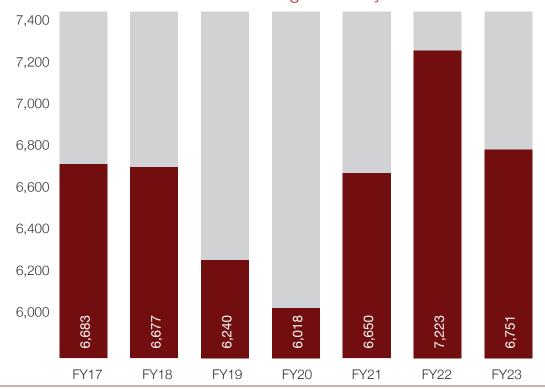
- Drug Distributors (89, -31%)
- Drug Distributor Registrants (6, +20%)
- Drug Outsourcers (5, No Change)
- Intern Pharmacists (359, -2.4%)
- Pharmacies (350, +66%)
- Pharmacists (Active and Inactive) (457, -10.9%)
- Pharmacy Technicians (5,439, -8.5%)
- Temporary Pharmacists (7, -30%)
- Third-Party Logistics Providers (39, -14.7%)







# New Licensees/Registrants by FY

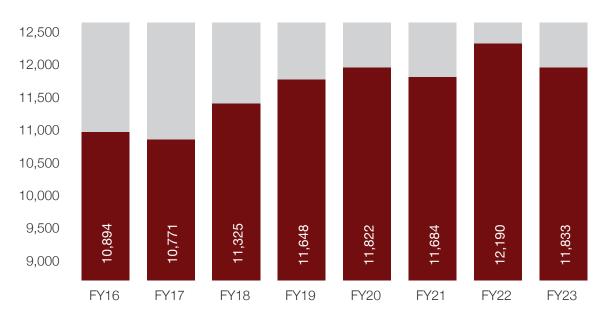


# Licensing



#### Pharmacists:

Total licensed pharmacists decreased by 2.9%:



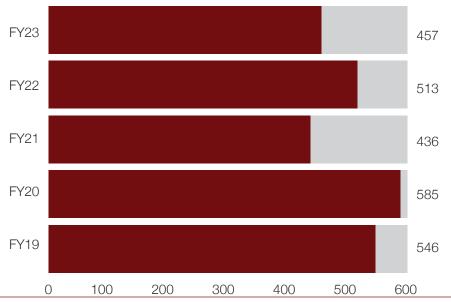
Active vs. inactive Missouri pharmacists are reflected below (resident and non-resident):

Active Licensees	11,549
Inactive Licensees	284
TOTAL LICENSED PHARMACISTS	11,833

<sup>\*\*</sup>Inactive pharmacists are not authorized to practice in Missouri but remain licensed. Pharmacists are only allowed to go inactive during the renewal period.

#### Number of New Pharmacist Licenses Issued

Newly licensed pharmacists decreased by 10.9%:





### Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 60.6% of pharmacists reported a Missouri address as reflected below:

Resident Pharmacists	7,008
Non-Resident Pharmacists	4,541
Total Missouri Resident Pharmacists	11,549

#### Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri-licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 23:

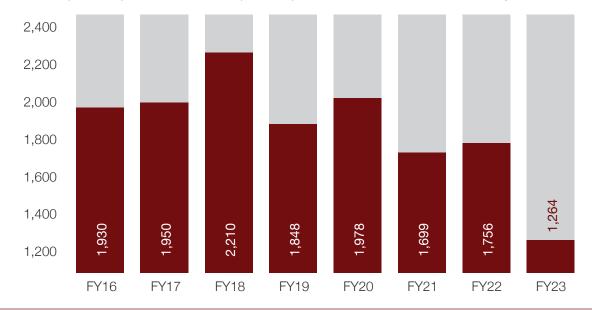
- 3,160 pharmacists were authorized to administer medication by prescription, representing a 12% decrease from FY
   22.
- 3,470 pharmacists were authorized to administer immunizations by protocol, representing a similar 13.7% decrease.

#### Medication Therapy Services:

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 3,823 pharmacists held a MTS certificate at the end of FY 23 (+2.4%).

#### Intern Pharmacists:

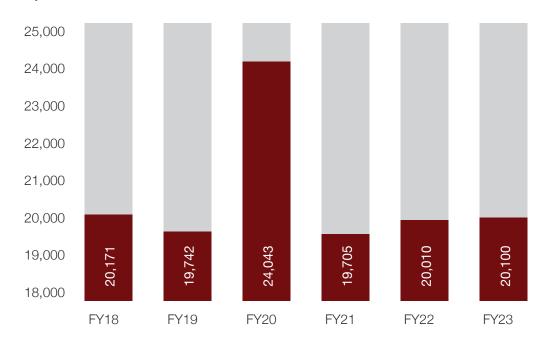
Total intern pharmacists decreased by 28% representing the largest decline in recent fiscal years. However, newly licensed intern pharmacists experienced a smaller 2.4% decrease (359 new licensees). Significantly, the decrease in newly licensed intern pharmacists was significantly lower than the 23.8% decrease in FY22 which was consistent with the 16.3% nationwide decline in pharmacy school students reported by the American Association of Colleges of Pharmacy.





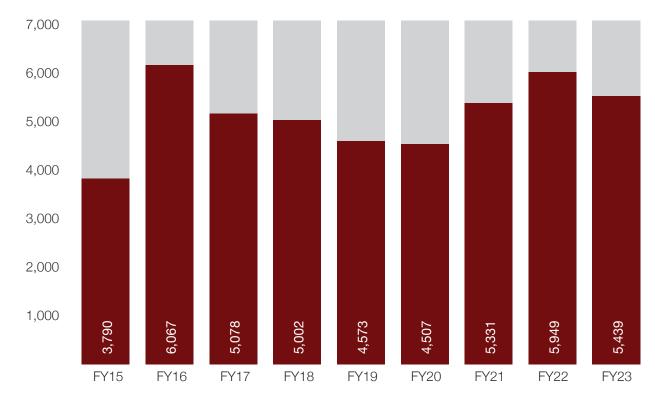
### Pharmacy Technicians:

Registered pharmacy technicians remained consistent with a minor 0.44% increase.



# New Pharmacy Technician Registrations Issued

New pharmacy technician registrants decreased by 8.5%, in contrast to increases in both FY 21 and FY 22.



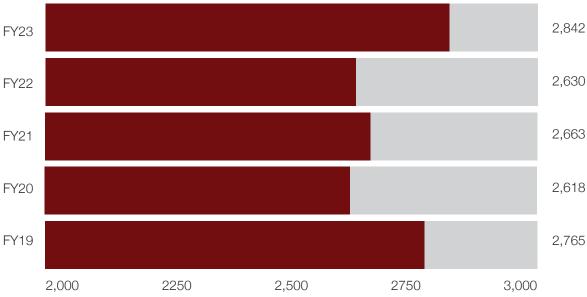


### Pharmacy Summary:

PHARMACY PERMIT TOTALS					
Instate Pharmacies	1,443				
Non-Resident Pharmacies	1,324				
Temporary Pharmacies	75				
TOTAL	2,842				

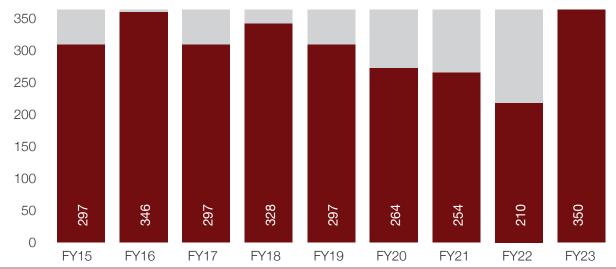
Total pharmacies increased by 8% (in-state and non-resident).

### Pharmacy Permitholders By Fiscal Year



### New Pharmacy Permits Issued

New pharmacy permits increased by an uncharacteristic 66.6%, attributable to an increase in non-resident pharmacy applications submitted by a national pharmacy chain in FY 23 to accommodate nationwide shared service/central fill activities.



# Licensing



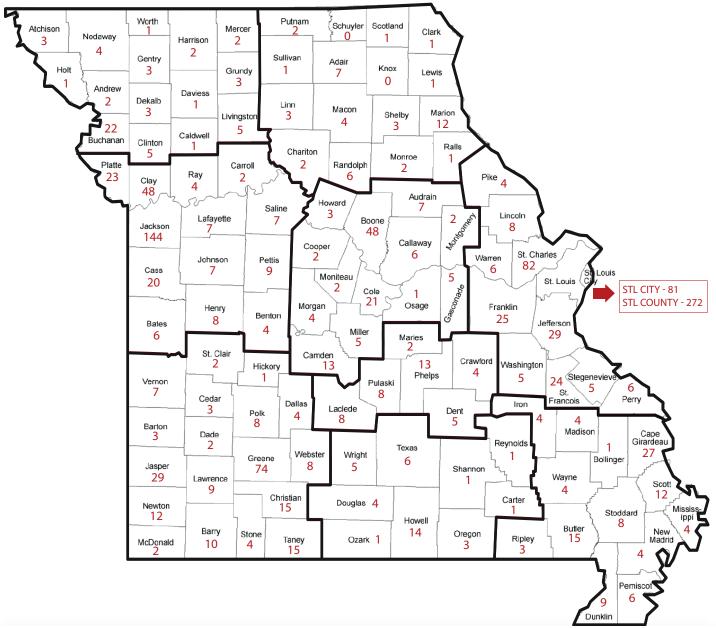
# Pharmacy Permits by Classification\*

(The below totals will not equal the total # of licensed pharmacies. Pharmacies may hold multiple classifications and could be reflected in more than one category).

(Pharmacies by Classification)	
Class A: Community/Ambulatory	2,214
Class B: Hospital Pharmacy	167
Class C: Long-Term Care	933
Class D: Nonsterile Compounding	768
Class E: Radiopharmaceutical	31
Class F: Renal Dialysis	11
Class G: Medical Gas	10
Class H: Sterile Compounding	375
Class I: Consultant Services	24
Class J: Shared Services	1,409
Class K: Internet	45
Class L: Veterinary	64
Class M: Specialty (Bleeding Disorder)	147
Class N: Automated Dispensing System (Health Care Facility)	21
Class O: Automated Dispensing System (Ambulatory Care)	0
Class P: Practitioner Office/Clinic	0
Class Q: Charitable Pharmacy*	1
Class R: Remote Dispensing Site Pharmacy*	9



### Missouri Pharmacies by County



#### Statistics to Note:

- · Two Missouri counties do not have a licensed pharmacy (Schuyler, Knox), an increase of 1 county (Knox)
- Sixteen (16) counties have only (1) licensed pharmacy: Bollinger, Caldwell, Carter, Clark, Daviess, Hickory, Holt, Lewis, Osage, Ozark, Ralls, Reynolds, Scotland, Shannon, Sullivan, and Worth
- The following nineteen (19) counties/areas experienced a decrease in licensed pharmacies in FY23, versus 16 counties in FY22:
  - Buchanan (-1)\*
  - Camden (-1)\*
  - Cape Girardeau (-3)\*
  - Carroll (-2)
  - Cass (-1)
  - Clay (-2)\*

# Licensing



- Dunklin (-1)
- Franklin (-1)
- Greene (-2)
- Jackson (-6)
- Jasper (-1)
- Jefferson (-1)
- Johnson (-1)
- Knox (-1)
- Lewis (-1)
- Moniteau (-1)
- Morgan (-1)
- Perry (-2)
- Pike (-1)
- Polk (-1)
- Saline (-1)
- Scotland (-1)
- Scott (-1)
- St. Louis City (-4)

<sup>\*</sup>Counties also declined in FY 22.

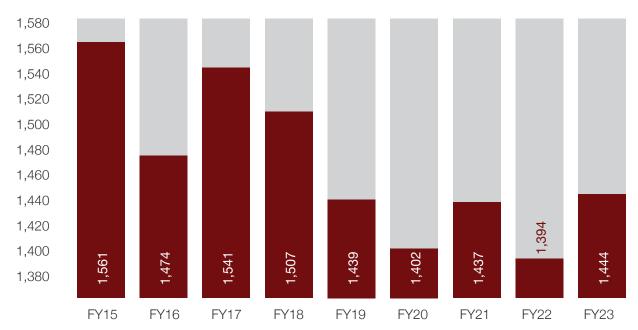


### Drug Distributor Summary:

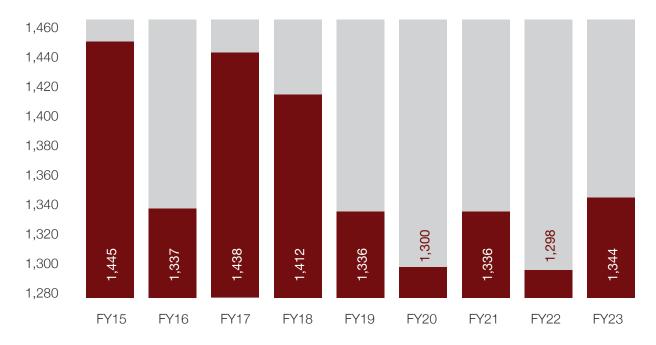
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug related devices into Missouri must hold a Missouri drug distributor license.

#### TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

Total licensed drug distributors and drug distributor registrants remained consistent with a minor 3.6% increase (1,344 drug distributors and 100 drug distributor registrants).



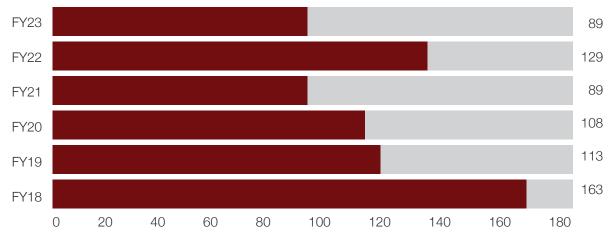
#### TOTAL DRUG DISTRIBUTORS BY FY





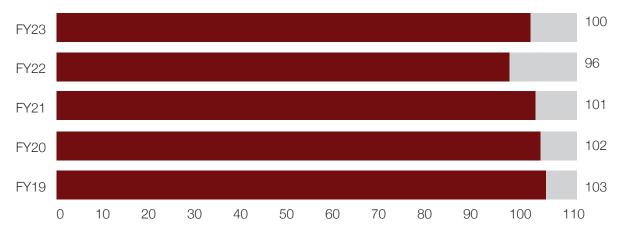
#### NEW DRUG DISTRIBUTORS LICENSED

Newly licensed drug distributors decreased by 31%:



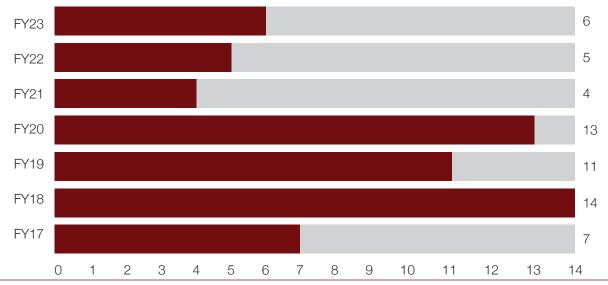
#### TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY

Total drug distributor registrants remained consistent:



#### **NEW DRUG DISTRIBUTOR REGISTRANTS**

The number of new drug distributor registrants remained historically low:





### DRUG OUTSOURCERS/THIRD-PARTY LOGISTICS PROVIDERS

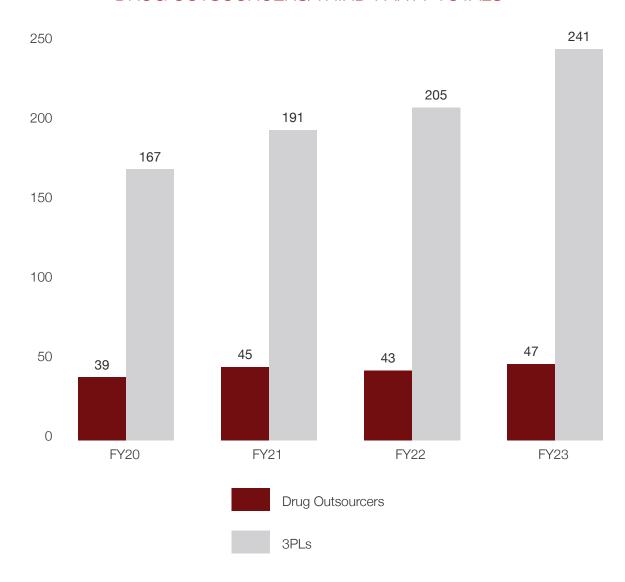
The Board began issuing drug outsourcer and third-party logistics provider (3PL) licenses in the fall of 2018

- Total 3PL licensees increased by 17.5% [205 (FY22); 241 (FY23)]
- Total drug outsourcers similarly increased by 9.3% [43 (FY22); 47 (FY23)]

New applicants for both license classes remained historically low:

- New 3PL licensees [FY22 (34); FY23 (39)]
- New drug outsourcer licensees [FY22 (5); FY23 (5)]

#### DRUG OUTSOURCERS/THIRD-PARTY TOTALS



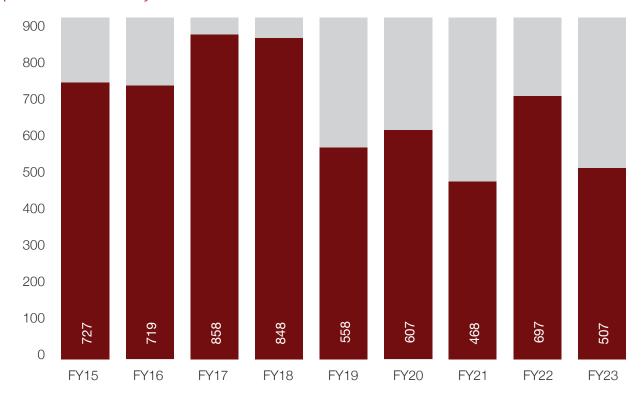
# Complaint Summary



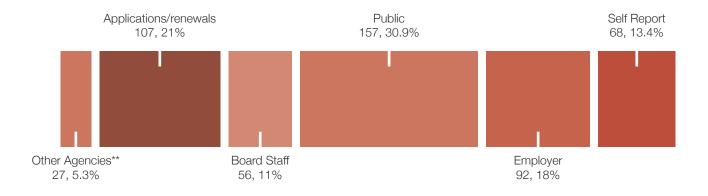
### **Complaint Summary**

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 507 new complaints in FY 23, representing a 27.2% decrease from FY 22. The decrease is primarily attributable to a decline in pharmacist audit complaints given FY 23 was not an audit year. Additionally, no tax compliance cases/complaints were referred from the Missouri Department of Revenue during FY 23.

### Complaints Handled by FY



# Complaints by Source





# FY23 COMPLAINTS BY CATEGORY

Advertising or Marketing	2
Compounding	8
Confidentiality	5
Criminal History	26
Disciplinary Action in Another State	70
Dispensing Error	23
Drug Distribution	4
Drug Diversion	28
Drug Losses	7
Expired Drugs in Active Inventory	1
Fraudulent Prescription	3
Fraud - Unspecified	1
Immunization/Administration	10
Impairment/Addiction	12
Improper Controls/Security	57
Improper/Unauthorized Dispensing	57
Incompetence	1
Inspection Violations	5
Insurance Fraud	3
Licensure Applicant	78
Other	4
Pharmacy Permit Violations	6
Prescription Transfers	5
Recordkeeping	1
Repackaging/Prepackaging	1
Sexual Misconduct	7
Theft (Non-drug)	27
Unlawful Drug Use	1
Unlawful/Illegal Sales	1
Unlicensed Activity	31
Unprofessional Conduct	15
Unsanitary Conditions	4
Violation of Discipline	3
TOTAL	507

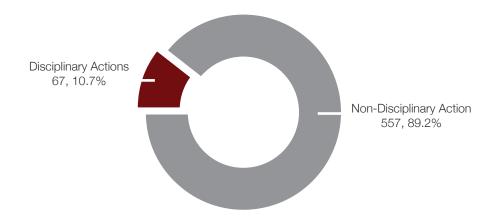
# Complaint Summary



#### COMPLAINT DISPOSITIONS

The Board issued final dispositions on 624 complaints/cases in FY23. All of the closed complaints/cases were non-tax related.\*

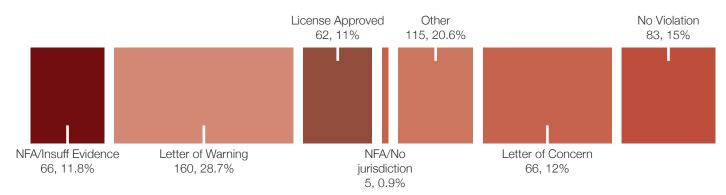
### (Non-Tax Related Complaint Dispositions)



<sup>\*\*</sup>Complaint dispositions includes complaints received in prior fiscal years but finally determined in FY23. As a result, complaint dispositions in FY23 will not equal the number of new complaints received.

#### SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 557 non-tax related complaints closed without disciplinary action in FY23 (see Disciplinary Action section for disciplinary information):

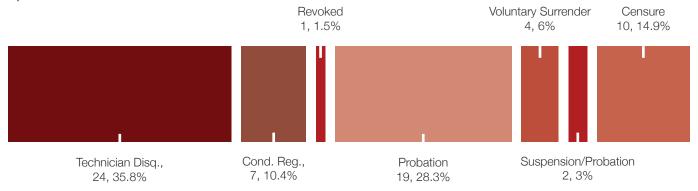


<sup>\*</sup> Other: Cease and Desist Letter (5), Closed (19), Closed but Flagged for Future Review (13), Closed- No Missouri Impact (76), Non-Administrative Letter (1), License Denied (1).



### Summary of Disciplinary Action

The Board issued sixty-seven (67) practice related disciplinary actions in FY23, representing a 14% decrease in Board discipline as reflected below:



#### DISCIPLINARY ACTIONS BY CATEGORY

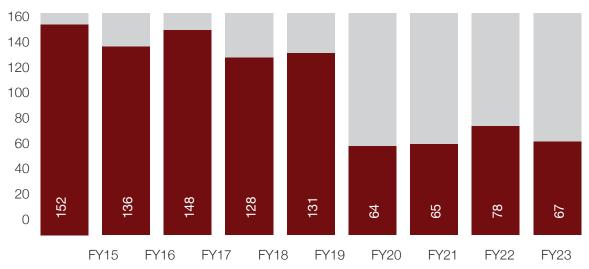
Drug Distributors Probated	3
Drug Distributors Censured	3
Intern Pharmacists Voluntarily Surrendered (Treated as Discipline)	1
Pharmacist Licenses Censured	1
Pharmacist Licenses Probated	5
Pharmacist Licenses Revoked	1
Pharmacist Licenses Suspended Followed by Probation	2
Pharmacist Licenses Voluntarily Surrendered (Treated as Discipline)	2
Pharmacy Permits Censured	6
Pharmacy Permits Probated	11
Technicians Disqualified	24
Technicians Placed on Conditional Employment	7
Technician Registration Voluntarily Surrendered (Treated as Discipline)	1
TOTAL	67



#### PRACTICE RELATED DISCIPLINARY ACTIONS \*

Thirty-two (32) pharmacy technicians, 11 pharmacists, 17 pharmacies, 6 drug distributors and 1 intern pharmacist were disciplined for practice-related issues during FY 23. Total disciplinary actions decreased by 14%, however, disciplinary actions continued to remain historically lower.

### (Total Practice-Related Disciplinary Actions by FY)

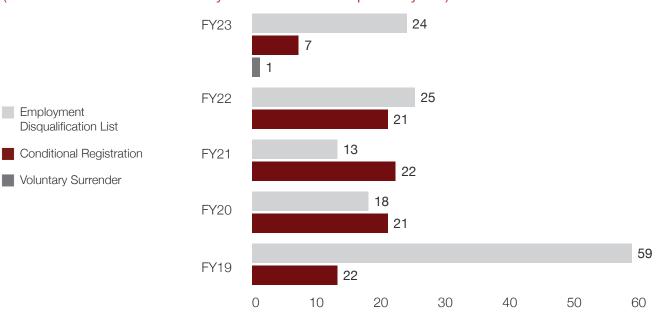


<sup>\*</sup> Does not include tax suspensions pursuant to § 324.010, RSMo.

#### PHARMACY TECHNICIAN DISCIPLINE

Thirty-two (32) pharmacy technicians were disciplined for practice-related reasons, comprising 47.8% of all practice-related disciplinary actions issued by the Board.

### (Practice Related Pharmacy Technician Discipline by FY)





# GROUNDS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION (Cause for EDL / # Disciplined)

- Criminal History (4)
- Diversion/Attempted Diversion (15)
- Diversion & Criminal History (1)
- Illegal Drug Usage/Positive Drug Test (1)
- Impairment/Suspected Impairment (1)
- Theft (Non-Drug Related) (2)

# GROUNDS FOR TECHNICIAN CONDITIONAL REGISTRATION (Cause for CR/ # Disciplined)

- Criminal History (1)
- Illegal Drug Usage/Positive Drug Test (1)
- Misconduct (Dispensing Related) (1)
- Prior Discipline (1)
- Theft (Non-Drug Related) (2)
- Unlicensed Activity (1)

#### PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline decreased by 38.8% from FY 22. Significantly, the total number of disciplined pharmacists in FY 23 represents 0.09% of total Missouri-licensed pharmacists.

	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23
Censure	6	6	3	11	5	2	6	1
Probation	14	13	15	10	6	8	6	5
Suspension	0	0	0	0	0	0	0	0
Suspension/Probation	4	0	1	0	2	5	1	2
Revocation	3	1	1	1	2	1	1	1
Voluntary Surrender (treated as discipline)		4	1	4	1	2	4	2
TOTAL	27	24	21	26	16	18	18	11



#### PHARMACY DISCIPLINE BY FY

Pharmacy discipline increased by 88.8% as reflected below, although total disciplinary actions remained historically low:

	FY19	FY20	FY21	FY22	FY23
Censure	0	1	0	2	6
Probation	15	5	6	7	11
Revocation	0	0	0	0	0
Voluntary Surrender	1	2	0	0	0
TOTAL	16	8	6	9	17

#### DRUG DISTRIBUTOR DISCIPLINE BY FY

Total drug distributor/drug distributor registrant disciplinary actions remained historically low, as reflected below:

	FY19	FY20	FY21	FY22	FY23
Censure	0	0	0	1	3
Probation	6	1	3	3	3
Voluntary Surrender	0	0	0	0	0
TOTAL	6	1	3	4	6

# Inspections/Investigations

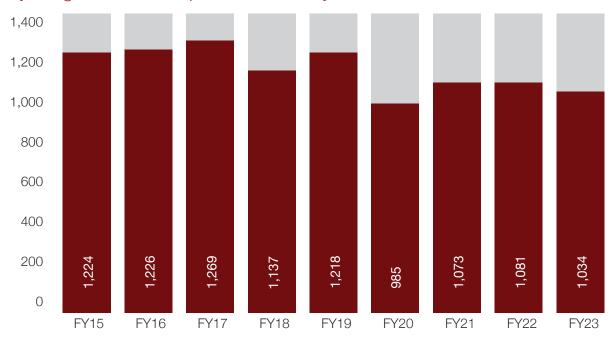


### Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies, drug distributors, drug outsourcers and third-party logistics providers. Board inspectors also conduct investigations as assigned.

- 1,034 regulatory inspections were conducted during the fiscal year, representing a 4.3% decrease from FY22 attributable to inspector retirement/vacancies. However, total completed investigations increased by 8.7% to 285 completed investigations.
- 881 pharmacies, 135 drug distributors, 2 drug outsourcers, and 16 third-party logistics providers were inspected during the fiscal year. Fifteen (15) drug distributors and one (1) third-party logistics provider were exempt from inspection as state-owned facilities or as authorized by 20 CSR 2220-5.040/20 CSR 2220-8.050 for facilities inspected by the U.S. Food and Drug Administration.

### Pharmacy/Drug Distributor Inspection Summary



#### INSPECTION FINDINGS

At the conclusion of an inspection, an inspector may initiate one of the following resolutions:

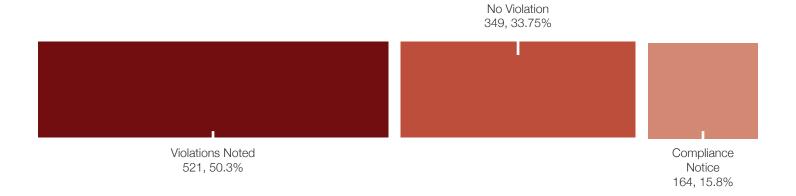
- Observation Report: Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- Compliance Notice: Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- Quality Assurance Report: Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- Investigation: An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.

# Inspections/Investigations



#### FY23 INSPECTION RESULTS\*

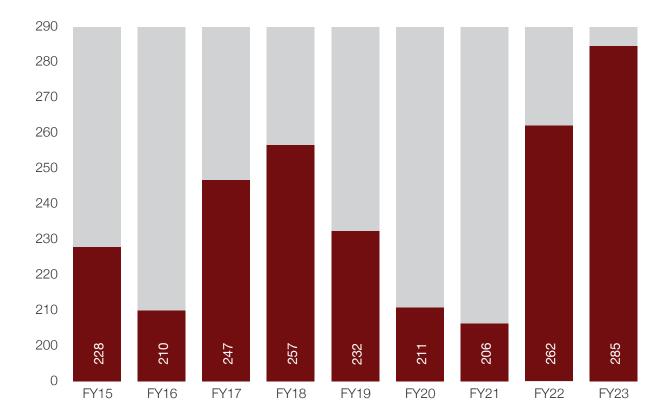
Approximately 66.2% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:



Inspection results in each category remained statistically consistent (e.g., no violation, violations noted, compliance notices).

### FY 23 INVESTIGATION SUMMARY

Total completed investigations increased by 8.7% to 285 completed investigations during the fiscal year.



<sup>\*</sup> Includes inspection results for follow-up inspections and investigations.

# Compounded Drug Testing



### **Testing Summary**

Pursuant to § 338.150, RSMo, the Board operates a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2023:

Dosage Form	Tests Performed
Capsule	28
Oral suspension/Syrup	9
Topical Cream	8
Injection	7
IV Solution	7
Troche	2
Sublingual Tablet	1
Suppository	1
Tablet	1
Vaginal cream	1

Test Results	Tests Performed	Percentage
Satisfactory	46	70.8%
Unsatisfactory	19	29.2%
Total	65	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 42.8 to 154.8%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Drugs With Unsatisfactory Results
Biest
Biest/Progesterone
Biest/Progesterone/DHEA
Biest/Progesterone/Testosterone
Biest/Progesterone/Testosterone/DHEA
Biest/Progesterone/Testosterone/Pregnenolone
Dantrolene
Estradiol
Hydrocodone Bitartrate/Phenylephrine/Chloropheniramine
Ivermectin
Ketoprofen/Baclofen/Cyclobenzaprine/Lidocaine
Norepinephrine
Vancomycin

# Rulemaking



### Rule Changes

The Board continued its ongoing review of Board rules to ensure appropriate and consistent regulation and to adopt a standards of practice approach focused on:

- · Establishing standards of practice to ensure patient safety
- · Eliminating unnecessary regulatory requirements, and
- · Maximizing pharmacist skill, training and education to enhance patient access to care.

The following rules were promulgated/amended by the Board in FY23:

20 CSR 2220-2.120	Pharmacy Standards of Operation	Updated general pharmacy operational standards			
20 CSR 2220-2.011	Electronic Final Product Verification (Pharmacists)	Allowed pharmacists to perform electronic product verification using qualifying technology			
20 CSR 2220-2.012	Technology Assisted Prescription/Medication Order Verification (Intern Pharmacists & Pharmacy Technicians)	Allowed pharmacy technicians/intern pharmacy to perform technology assisted prescription/ medication order verification under the supervision of a pharmacist			
20 CSR 2220-2.090	Pharmacist-In-Charge	Updated and clarified pharmacist-in-charge supervisory responsibility and allowances/requirements			
20 CSR 2220-2.200	Sterile Compounding	Removed requirement for duplicate Risk Level 3 sterility/endotoxin testing to prevent medication shortages. *Previously filed as emergency rule.			
20 CSR 2220-2.200	Sterile Compounding	Allowed portability of aseptic technique skill assessments for pharmacy staff subject to Board requirements. *Previously filed as emergency rule.			
20 CSR 2220.2.685	Standards of Operation for a Class Q: Charitable Pharmacy	Established licensing requirements and standards of operation for Class Q Charitable pharmacies			
20 CSR 2220.6.025	HIV Post-Exposure Prophylaxis	Established requirements for pharmacist dispensing of HIV post-exposure prophylaxis as authorized by § 338.730, RSMo			

# Rx Cares for Missouri



### Rx Cares Program Overview

The Missouri General Assembly enacted § 338.710 in 2017 which created the Rx Cares for Missouri Program within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. Rx Cares Program funding is appropriated annually by the Missouri Legislature. The Board expended \$ 144,476.55 in FY 23 on the following Rx Cares program activities:

#### Rx Cares Medication Destruction Program

The Rx Cares program was enacted simultaneously with § 338.142, RSMo, which granted the Board authority to establish a drug take-back program for controlled substances, in consultation with the Missouri Department of Health and Human Services. The Board subsequently established the statewide Rx Cares for Missouri Medication Destruction and Disposal Program for the collection of unused/unwanted medication. The medication destruction/disposal program plays a critical role in combating the opioid epidemic by providing safe options for patient disposal of unused or unwanted medication.

Pursuant to state contract, the medication destruction/disposal program is managed/operated by Sharps Compliance® under the supervision of the Board. Eligible program participants include:

- A licensed Missouri pharmacy or drug distributor
- A licensed healthcare provider authorized to prescribe controlled substances
- · A hospital, office, clinic, or other medical institution that provides health care services
- A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or
- A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education. [20 CSR 2220-2.990]

Board approved program participants are provided a medication collection receptacle that complies with state and federal controlled substance laws. Collected medication can be mailed/submitted to an approved Sharps Compliance® vendor up to twelve (12) times per year at no cost to the participant.

- Expenditures for the medication destruction/disposal program totaled \$51,590 in FY 23
- One-hundred and seventeen (117) entities were approved to participate in the medication destruction/disposal program in FY 23, including, pharmacies, hospitals, and local law enforcement agencies\*\*
- Approximately 15,517 pounds of unwanted medication were destroyed in FY23; A total of 36,826.56 pounds of unwanted medication since program inception\*\*

<sup>\*\*</sup>Data as of July 25, 2023.

# Rx Cares for Missouri



# Rx Cares Grant Program

Section 338.710, authorizes the Board to expand, allocate or award funds appropriated to the Board to provide programs or education to promote the Rx Cares Program goals. The following Rx Cares grant funding was awarded in FY22:

Recipient	Description	
Alps Pharmacy (Continued from FY22)	Providing Dispill adherence packaging to patients to facilitate medication adherence and prevent medication errors	
Butler Drug Store (Continued from FY22)	Rescue MO Lives Educational Program: Goal is to decrease the # of patients suffering from opioid abuse and misuse in Southeast Missouri by providing patient education on safe opioid use/practices and naloxone.	
Ste. Genevieve Community Services Forum (Continued from FY22)	Community and student drug safety educational program. Program activities include: (1) "Stop the Stigma" educational initiative, (2) prevention educational activities for ages 9-12, and (3) August 2023 substance awareness, (4) facilitation of drug takeback programs, and (5) collaboration with Ste. Genevieve County Memorial Hospital to monitor/trend benzodiazepine and opiate prescriptions.	
Taney County (Continued from FY22)	Taney County Alcohol and Drug Abuse Prevention Team (ADAPT). Youth and elderly focused safe medication, storage and usage program. Program operated in collaboration with UMKC pharmacy school, law enforcement agencies, and Community Partnership of the Ozarks.	\$12,073.00
Washington University	Inter-disciplinary research to investigate the feasibility of community health worker-pharmacy led interventions to increase patient engagement and retention in innovative strategies of harm reduction. Grant funding will include a pilot cluster randomized hybrid type II clinical trial. Project operated in collaboration with UMKC, St. Louis College of Pharmacy, Washington University, and the Missouri Pharmacy Association.	\$42,931.50
	TOTAL AWARDED GRANT FUNDING	\$92,789.52

FY22 Appropriation



# **Rx CARES FOR MISSOURI FY23 FINANCIAL SUMMARY**

Legislative Appropriation	\$	750,000.00	
Adjustments/Refunds	\$	-	
			\$ 750,000.00
Funds Expended**			
Grant - Alps Pharmacy	\$	11,823.00	
Grant - Butler Drug Store, Inc.	\$	13,466.20	
Grant - Community Foundation of the Ozarks	\$	12,073.00	

Grant - Ste. Genevieve Community Services Forum \$ 12,495.82

Grant - Washington University/Missouri Pharmacy Assoc. \$ 42,931.50

Misc. - UPS Mailing Costs \$ 97.03

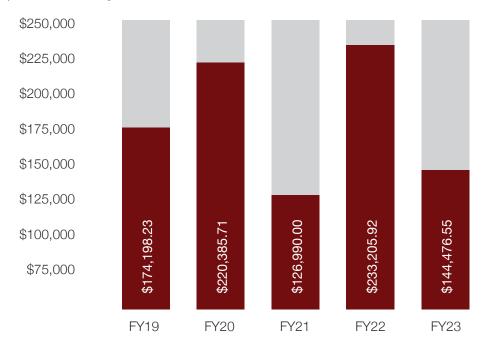
Sharp's Compliance (Medication Destruction Program) \$ 51,590.00

**Total Expenses** \$ 144,476.55

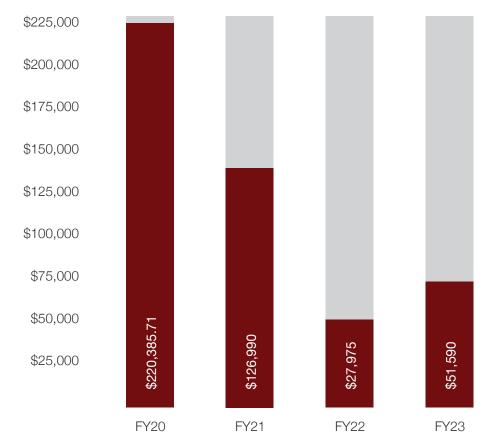
<sup>\*\*</sup> Grants awarded in FY23 and expended grant funds will not be equal due to tiered payment schedules. Rx Cares funds may be awarded and expended in different fiscal years.



### Rx Cares Expenditures by FY



# Rx Cares Medication Destruction Funding



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